

**Medical Board of California (MBC) and Board of Registered Nursing (BRN)
Forum on Public Safety and the Use of Lasers for Cosmetic Procedures
(Business & Professions Code Section 2023.5)**

LASER FORUM MINUTES

Date: September 13, 2007
Time: 9:00 a.m.
Location: Department of Consumer Affairs
1625 North Market Blvd., N217
Sacramento, CA 95834

Members Present:

Susanne Phillips, R.N., Board of Registered Nursing
Jane Solomonson, M.D., Medical Board of California

Staff Present:

Kurt Heppler, Legal Counsel, MBC
Harry Gibbons, Legal Counsel, BRN
Heidi Goodman, Assistant Executive Officer, BRN
Linda Whitney, Chief of Legislation, MBC
Renee Threadgill, Chief of Enforcement, MBC
Elliot Hochberg, Enforcement Program Manager, BRN
Janette Wackerly, MBA, RN

Agency Employees present:

Glenn Mitchell, Physician Assistant Committee
Patti Mahan, MBC
Marcie Bannon, MBC
Susan Cady, MBC
Erlinda Suarez, MBC
Jose Guerrero, Attorney General's Office

Audience Present:

Terri Thomas, Thomas Advocacy Inc. for American Laser Centers
Donna Fox, CNA
Jack Bruner, MD., California Society of Plastic Surgeons
Tim Madden, Society of Plastic Surgeons
Cecily Cosby, California Association of Nurse Practitioners,
Thomas Cutillo, Samuel Merritt College
Gina Nguyen, Samuel Merritt College
Mina Tekeske, Samuel Merritt College, PNP Student
Marylyn Hagerty, Aesthetic Trends Institute
Selam Cebierghi, FNP Student
Paul Batcher, Center for Public Interest Law
Kris Rosa, Noteware Government Relations

Fred Noteware, Noteware Government Relations
Connie Hoy, Cutera, Inc.
George Cate, Senate B & P Committee
Anu Verma, RN, Radiant-Images Laser Center
Lisa Faer, RN, Munyon Dermatology, Inc.
Lydia Bourne, California Nursing Association
Joan Goss
Kay Weinkam, BRN
Others present, but not identified.

The meeting was called to order at 9:00.

1. Welcome - Introductions

Susanne Phillips, member of the Board of Registered Nursing, welcomed everyone to the second joint meeting of the MBC and BRN. Introduction of the staff members from both departments was made and the purpose of the forum, which is to gather information about the current practice environment that utilizes lasers and intense light pulse devices for cosmetic procedures, was given.

2. Overview of Charge - Business & Professions Code Section 2023.5

Dr. Solomonson reviewed B & P Code Section 2023.5 which charges the Medical Board of California and the Board of Registered Nursing to study the safety of lasers and intense pulse light devices for cosmetic procedures. The law enumerates a number of things that are to be examined, including appropriate level of physician supervision, the appropriate level of training, and guidelines for standardized procedures. The law directs the boards to examine the use of topical agents, adequate patient informed consent, follow-up care, and emergency issues. If, after the Boards' complete their examination, new regulations are deemed necessary, they must be promulgated by January 1, 2009. By that date, the boards will also report their findings to the Legislature. A copy of the law was available to all attendees.

Dr. Solomonson explained that the purpose of the forum is to gather information, only. The forums are not official Board meetings; therefore the group conducting the forum is not authorized to take any action. It is the second meeting and the focus is on public safety. She acknowledged the tremendous profitability of cosmetic procedures, and stated that because of that, discussions might be derailed in order to address various issues not relevant to public protection. Our mutual Boards' focus is on public protection, and for that reason we ask that you assist us with resisting such detours by reviewing your presentations and/or comments and keep the focus on the issue of safety.

Today and at the next scheduled meeting on October 31, 2007 in San Diego, California, we will gather information. Staff will write a report of findings to be presented to our separated boards, and our board members will decide the next course of action.

They may set-up board committees or working groups, or simply decide on mutual staff recommendations. We cannot, at this time, predict the outcome. All of our meetings are public, and any materials presented to the members will be public. Before any action can be taken, interested parties will be given the opportunity to weigh-in with their comments. If regulations are promulgated, they will be subject to

the formal rulemaking process, which provides a public comment period and a public regulatory hearing.

Today, we have asked a number of groups and individuals to present testimony. If any of you here today who are not scheduled for a formal presentation, but wish to comment, we ask that you sign in, and your comments will be heard during the public comment section of the agenda. If you wish to be given ample time to make a full presentation at the next meeting, please see Janie Cordray or Janette Wackerly.

We will begin taking testimony and are hoping to keep presentations to a minimum of 20 minutes, as there are numerous presentations to be made. Any written material provided will be included in the official record and made available to the public in addition to the minutes.

3.0 Review of August 30, 2007, Forum Discussions – Susanne Phillips

On August 30, 2007, the Medical Board of California and the Board of Registered Nursing held their first public forum in Orange County, CA. Minutes of that meeting, as well as, all of the materials provided, will be available on the Medical Board's website, and the Board of Registered Nursing's website.

At the meeting, we heard from a number of organizations and individuals. Norm Davis and Alan Voss shared their experience with the legal issues surrounding the use of lasers. Physician Assistants, Jennifer Faggionato and Ann Davis spoke on behalf of the American Academy of Physician Assistants, and the California Academy of Physician Assistants. Beth Haney, California Association of Nurse Practitioners, Trisha Hunter, American Nurses Association/California, and Donna Fox represented the California Nurses Associations.

A number of physician organizations made presentations as well. Dr. Jerry Potazking and Dr. Christopher Zachary represented the California Society of Dermatologists and the American Society of Dermatologic Surgery. Dr. Brian Kinney spoke on behalf of the California Society of Plastic Surgeons. Dr. James Newman represented the California Society of Plastic Surgeons. Dr. James Newman represented the California Society of Facial Plastic and Reconstructive Surgery.

In addition to those who were scheduled to make formal presentations, a number of individuals provided public comment.

While no action is being considered at the forums, the presentations and the comments had a recurring theme: new laws and regulations may not be needed, but there must be enforcement of current laws and regulations. For this reason, the group has directed our staff to prepare a white paper on the current laws and how they are enforced, and what needs to be done to ensure public safety. New laws or regulations will be meaningless if the current ones are not being enforced. Janie Cordray will prepare and present the paper at the next Forum in San Diego on October 31, 2007.

4.0 Testimony: Representative of the Laser Industry

- Alan Voss, A.L. Voss & Associates
Independent Business and Regulatory Consultant
(Handouts were provided)

Mr. Voss thanked the members for another opportunity to speak. Mr. Voss has been in medicine for over 35 years, and in the last eight years has been a consultant working on issues related to medical devices and the use of those devices by individuals, specifically those other than physicians. Mr. Voss shared data that would give members an idea of what is going on in other state's so that perhaps it may assist with future decisions, in California.

He stated that one of the regulation processes has been very, very confused. The problem being that historically companies developed prescriptive medical devices for use by physicians. However, we find that is not the case, and that the emergence of devices designed and being used by non-physicians has changed the practice environment.

People are now trying to find ways to deal with this problem. And, even more problematic is that they are not controlled by any single board. Regulations have been made in many States, by the administration control board, that have nothing to do with the clinical aspect, but because they do the inspections more often than facilities, they're the ones that told other boards what they think should be done.

In the city legislature, there have been many, many attempts to pass bills controlling device light procedures. Most of these have been driven, as you might expect by various political agendas and generally have not faired well. It's a most difficult and time consuming route and few states have successfully had this work for them. Most states have general statutes already in place, which will allow various regulatory boards who are really more in touch with the situation to be able to regulate.

The thing that's very interesting is the FDA, which a lot of people put their credence in, has really no control on the use of these devices. They control only the manufacture, what the manufacturer can sell the device for, and do not control its utilization. And so very often, if not almost 100% time initially, when these products came out, States really didn't know that it was their duty, nor did they have the experience to be able to deal with these particular devices. So generally, State regulatory boards determined under what level of control that may be used and the biggest problem also is that there are many different ways in which they do this. There is one which is by statute, which California has in place, for example, one of the very few states. There are those which have rules and regulations that are promulgated by boards through official processes. Then unfortunately, more of the states are regulating or controlling these devices by philosophies, opinions, or off the cuff whatever, which is very difficult because the practitioner's, whoever they are out there using it don't know exactly what the rules are because there's nothing they can go to, statute or regulation, that says yeah or nay.

Many of the State, if not most of the State regulatory boards did not know it was their responsibility to come up with this rules and regulations program. Different boards in the same State have different opinions so, as I said earlier, there is a lot of warfare going on. I can tell you there is more than one State where the Medical Board has one opinion and the Board of Cosmetology says "no, we don't agree, their licensees can do whatever their board says". There's little or no expertise at most boards on the subject. There are minimal resources in these boards, whatever they may be to promulgate new regulations and it hasn't really been their chore, historically.

Different groups within these boards have very different opinions which of course make things even more difficult. Every board that is regulated is trying to figure out a way to do so. Is it based on procedure? Is it based on training? Is it based on the type of licensure, or does it depend on the type of scrutiny?

After speaking with boards and stakeholders over the last eight years, the fact is that laser treatments are not being performed by physicians, but rather by licensed healthcare staff. Every State has a little different determination on what non-evasive and evasive means. For example, years past, evasive meant penetration of something through the tissue or through the skin. Now, some people want to say, well light penetrates the skin, so it must be evasive. So, it depends upon definitions, which are again not standardized.

Everybody concurs that it requires the appropriate amount of training for all involved, and the current training is not adequate, and the current training by definition is almost always being produced or given by the manufacturer of the products. The big problem with the manufacturer's that even if they request everybody to be present during training, for example, if a physician is going to use the device or have it delegated to their staff, that they require everybody on staff who will be using it, as well as the physician, be there. If this takes place outside of the office, physicians who have a real battle with staying current with what's going on and keeping their practice going, wants CME units or something for these procedures, than manufacturers generally can't give those, so it becomes another problem. What we are seeing generally, physician onsite presence has had little to do with patient safety of the procedures.

The majority of these systems, therefore, are new and unfortunately even the physicians, whatever they're specialty, have a good chance of not being trained on these devices during their formal medical education. So, they're looking for a place to be trained as well, which unfortunately, right now, kind of goes back to the manufacturer of the product.

It appears that the majority of adverse events still stem from people doing it wrong. In other words, inappropriate training or not enough training. Regulatory boards want more control and better product training, but aren't quite sure how to go about it. Insurance companies are now weighing in, requiring proof of the amount of training received, to ensure that individuals using these devices can do so safely. Again, how do they get this training? Historically, it's been through the manufacturers.

In closing, Mr. Voss stated that this an important issue, a controversial issue, it's one that has many different groups and stakeholders which have very valid opinions and it's important that you listen to all of them but make sure that it's going to be workable and enforceable when it's all done.

➤ **American Laser Centers**

Mr. Kevin Piech, Chief Administrative Officer
(Handouts were provided)

Mr. Piech thanked the Boards for the opportunity to speak. American Laser Centers is the largest provider of laser treatments in the country. There are over 200 affiliated centers nationwide and operate in 31 States, and Puerto Rico. In the month of

August, American Laser Center provided over 100, 00 treatments. They have 50 sites in California, and safety is an utmost concern. In California, all sites are physician owned, and safety is the number one concern. It is important for the physicians because their medical license is at stake, on how American Laser delivers services, but it is also simply good business practice. Most injuries occur in centers where current regulation should have been enforced, and could have prevented those injuries. The public should not be afraid of what is a safe procedure. American Laser believes that this is a service that when properly done should be available to all. It's bad operators, those who are unlicensed and those who do not have adequate training that American Laser would like to see out of business.

American Laser Centers supports the work the boards are doing and would welcome the opportunity to give input as they can on how these services can be delivered safely and effectively.

Some State's have attempted to over regulate due to severe injuries. American Laser Centers feels that the single most important factor is the training of the person operating the laser. If the MBC and BRN are serious about the safety of the public in California, efforts should be focused on requirements for training of the operators of the laser operators.

- **Strict Protocol**
American Laser Centers has written its own treatment protocol, and believe they have the safest, most effective protocol, which attributes to their low incident/injury rate.
- **Adequate Training**
American Laser Centers require more training than any State requires, specific to laser.
- **Effective Monitoring**
Monitoring is done by electronically charting enables them to look at the chart, evaluate, and are able to recommend the correct course of action immediately.

In closing, had the current regulations that are on the books right now, been enforced, you wouldn't see or hear some of the horror stories that will be presented today. Before considering adding additional regulations, enforce the already good regulations first.

Dr. Solomonson requested American Laser Centers training model and treatment protocol along with information on how the physician oversight is working in California.

➤ **Representatives of Nursing Associations**

Cecily Cosby, PhD, NP, California Association of Nurse Practitioners

Dr. Cosby thanked the members for the opportunity to speak. Dr. Cosby provided several articles on the quality of care that Nurse Practitioners have provided over the years.

Dr. Cosby concurs with the previous presenters in her belief that these procedures can safely be done by RN's and NPs, and the issue or question of safety is not credentials, necessarily, but certainly the training and the competency based training of individuals. She did a literature review on the incidents of adverse affects, if you look to the documentation, these are safe procedures and it is a question of the appropriate selection of candidates and the appropriateness of the technology and having some medical decision making abilities in terms of determining who are good candidates and when to proceed and when not to proceed. She worked collaboratively with a plastic surgeon, where she had an opportunity to provide these procedures and also train individuals who would be working in the facility. She believes there are some novelties ways of ensuring competency and is looking to the BRN and MBC to standardize the guidelines. Having a physician onsite does not guarantee safety. Having a physician on site does not guarantee safety. When you look at the number of laser and light base procedures that are done annually, and recognizing the growth in the marketplace, there may be eventually home laser equipment, so certainly safety and the appropriateness of legislation is important.

When we talk about the 1.3 million procedures, the majority of the procedures are done by non-physicians, so when we hear about adverse affects, it makes statistical sense that we determine these practitioners to be non-physician clinicians, however, I think we need to be rigorous about our understanding and terminology on who these non-physician providers are. Oftentimes, cosmetologists, dental assistants, technicians, non-licensed personnel are kind of lumped in the same group as registered nurses and nurse practitioners and physician assistants. So, she would ask that we speak to licensed personnel versus non-licensed personnel as opposed to talking about non-physician practitioners. And, if we are doing that, we are very clear about who we are referring to.

Dr. Cosby agrees that if the existing regulations, had they are enforced, would have certainly prevented or reduced the number of adverse affects that we've seen.

There is a difference in the scope of practice of registered nurses and nurse practitioners. The skill level, education, and training of nurse practitioners, physician assistants and other mid-levels, that does specifically address their ability and competency to do the exams, assess patients, gather appropriate history, and to make the determination of diagnosis and treatment. Nurse practitioners are uniquely qualified to work in this arena, for all of these reasons.

As clinicians we know how to prevent and reduce some of these adverse events, and certainly, any training that would be provided or required would include that. I think these are relatively safe procedures and when we train nurse practitioners and physician assistants to do other technical procedures, there are existing protocol requirements for directly observed procedures and competency and certainly there should be a minimum standard to assist us in establishing good, safest clinician who will be providing these treatments.

Lydia Bourne, American Nurses Association

Thanked the members for the opportunity to speak

The American Nurses Association feels that the laws that are currently in place are sufficient to meet the patient safety issues that are being discussed. Specifically, for

the Registered Nurse, there are standardized procedures that are clearly defined in the Nursing Practice Act, the Medical Practice Act and Title 22. Requirements are clearly spelled out, the relationship between the RN, physician and administration. The nine steps must be met to ensure patient safety and to prevent patient harm.

One issue that should be looked at is licensed vs. unlicensed personnel. ANA/C believes that standardized procedures and the nursing practice act are sufficient to provide guidance for RN's functioning in various types of facilities that provide laser surgery. One issue that has been brought up is the idea of the State licensing the facilities that provide these services. Once training requirements can be addressed for the unlicensed personnel, we can take a look at the licensing of the facilities that provide laser services.

Donna Fox, California Nurses Association

Thanked the members for another opportunity to speak. Ms. Fox summarized her comments by stating there may be a need to have regulations in this area. Relatively speaking, the use of lasers for cosmetic procedures is a risk, so the concern about public safety is paramount. The standardized procedure guidelines are to protect the consumer by providing evidence that nurse can practice safely and very importantly to provide uniformity in the development of the standardized procedures. That is clearly not the case, yet.

Again, Ms. Fox reiterated that the boards would do well to take a hard look at the regulation of the facilities that provide laser services. Increasingly patient healthcare and patient outcomes are affected by healthcare system factors, which is very important for patients and for healthcare providers.

➤ **Representatives for the Physician Assistant Organizations**

Deb Griffith, Physician Assistant, Chairperson of Government Affairs Committee and a member of the California Academy of Physician Assistants

The American Academy and California Academy of Physician Assistants provided testimony at the forum in Orange County, however, Ms. Griffith will be clarifying a couple of issues based on previous testimony.

CAPA supports the views of Dr. Newman from the California Society of Facial Plastic and Reconstructive Surgery on enforcing current legislation and laws and also very much support the idea of the patient bill of rights, however, the concern is there was no mention of certification of physician assistants in specialty areas.

California Society of Plastic Surgeons

A position paper was provided which outlined the concerns of the California Society of Plastic Surgeons.

The importance of physicians involved in treating patients with injuries involving laser treatment.

American Society for Dermatological Surgery

John Valencia, Attorney for the American Society for Dermatological Surgery and the California Society for Dermatology and Surgery.

Mr. Valencia gave preliminary remarks and re-presenting from a lay perspective, cases that have already been presented to the joint boards at the first hearing. Remarks will be from a lay perspective and from an enforcement perspective for that reason.

SB 1423 brings us here principally because of patient safety. Injuries occur and in all sets of circumstances. There is a general tendency to relegate cosmetic medical procedures to lesser status simply because of the word “cosmetic”. Laser based cosmetic medical procedures, laser based medical procedures can and have caused serious, permanent disfiguring results to patients. In what other aspect of medical care do you take a generally healthy individual who presents, who must first be injured in order to generate the desired outcome. That’s remarkable, that is fundamentally different, we think, from the balance of the practice of medicine.

He is in agreement with earlier speakers on the point that medicine, and this is what we are fundamentally talking about, can only be delegated to other allied health professionals by physicians and surgeons. Both boards have excellent guidance in print and on their website as to what circumstances that can occur under...what the settings are, about which there’s a great deal, I think not of confusion, but ignorance because delegation can only take place in an organized healthcare settings and the BRN and MBC are in agreement that as expansive as the Business and Professions Code is, it is not so expansive as to include an organized health settings i.e. beauty salons, spas, malls and unique settings, speaking charitably. Some of the settings described and some of the occasional degree of physician supervision is at best, questionable under existing law. He firmly agrees, given his experience in pursuing enforcement matters for both boards that we’re not talking about the entities where individuals that inspire to compliance, we’re talking about the worst of the worst that put patients at greatest risk.

The worst of the worst tend to exploit, or I suppose, as bad as anything else, be ignorant of the basic requirements in law. Corporate entities tend to pursue and exploit generally unsuccessfully the recruitment of so-called medical directors. They are recruited by corporate entities or individuals knowing or unknowingly to function in this medical director capacity in “supposed compliance” with California law. But we all know that isn’t California law because medical directors can only function in a corporate setting if that corporate setting is physician owned with other allied health professionals potentially being shareholders in that setting. But it’s not available to corporation x, y or z that is not physician owned, obviously the inference then is that the corporate entity would be operated and is certainly unavailable to the general layperson.

Corporations and sole entities are routinely ignorant of the balance of what is very comprehensive law in this area. Limits on advertising...how many laypeople know that the mere representation of the availability of medical care in their setting is in fact violation of the Medical Practices Act because only physicians and surgeons, only healthcare professionals can in fact advertise the availability and offering of those services. Yet, you find advertisements in newspapers, valpak coupon mailer, all of the various entities that advertise the availability of this care, without mention of physician involvement are presenting that type of advertising. Very few are aware of the fictitious name permit requirements. You can’t try to induce patient participation

and care in your setting with wonderful grand representations of what you are without mentioning that you're a healthcare setting. Very few who have advertisements go out, do a good job at compliance.

The beautiful models and the often misleading if not outright fraudulent before and after photos, or at least photos that represent themselves as before and after, fail to a) include the statement model, or b) simply state this is an actual patient and it's my actual patient, not some patient photos I borrowed from someone else, and that results may vary and that these may not be indicative of your outcome. That's why enforcement is in fact a priority and why we need to close the loophole that is exploited in this area.

On the question of enforcement, Dr. Brenner hit the nail on the head, as we're all aware that both boards are both understaffed and under-resourced when it comes to enforcement and there are some other competing, serious enforcement priorities. However, I would commend as a suggestion that you have available to you something that we as private practitioners don't, and that's the capacity to reach out through your board that you represent and also the Attorney General which often represents both boards and really work to encourage District Attorneys and City attorneys and their so-called consumer protection units (I call them so called because I have a sheath of "thanks, but it's not our problem letters") because I have routinely encouraged them and invited them to pursue, knowing the limitations of resources at both board levels, prosecution of consumer fraud, consumer injury and violations of the Medical Practice Act. There is no limitation to just these two boards in terms of patient safety that those entities can't and shouldn't be pursuing.

A slide presentation that was presented at the first hearing was reviewed. Most slides showed the scarring, disfiguring of patients due to failure to diagnose, misdiagnosis and inappropriate training on the use of equipment.

In conclusion, we believe the law is settled, medicine can only be delegated to allied health professionals under set circumstances. Only to train and license medical staff who are to treatment in organized health systems, a fundamental issue that is often blown by, by non-practitioners and those that are unaware of the actual requirements of California law. We firmly believe that onsite availability of physician supervision is a key, it's not the sole answer, but it's a key to in improving patient outcomes. We offer our creative approach to enhancing enforcement and will continue to assist the boards.

Dr. Craig President, C
(Slide presentation)

Dr. is a board certified Dermatologist practicing in Redding, California for over 10 years. He is president of the California Society of Dermatology

At the last hearing, a representative from a Laser company suggested that the dangers apparent in the unsupervised use of lasers by non-physicians are not statistically significant. His patient would like to be present to tell you herself, however, eventhough she voiced that from when he first started taking care of her from injuries she sustained by walking into a strip mall in Southern California and finding a warm body in a white coat that appeared confident in . She came in to shrink blood vessels on her face...they're easily removed, predictably no scarring, no down time,

nothing. People go into these places wanting to look better, end up looking worse and then realize that they were duped. It hurts their self esteem so much that most of them don't want to be in front of a board like this.

In Sacramento, laser light cosmetic surgery is being practiced by poorly trained and minimally or unsupervised business professionals. The result is injury to patients. There are many dangers in inadequate supervision, including, patient safety, with an increase in frequency of avoidable adverse actions, and of course, failure to treat adverse actions promptly and appropriately. Without supervision there is more often unnecessary or inappropriate laser services, which bring up the issue of over-treatment.

Unsupervised laser centers are a recipe for trouble. We've seen all the complications i.e. burns due to excessive treatment, scarring, delayed healing, erosion, discoloration, tattoo of the skin, eye injury.

In the end, it's all about patient safety.

The article published 9/06/07 was provided and presented as a slide presentation.

Dr. Christine Lee

Dr. Lee has board certification in dermatology and fellowship training in laser and cosmetic surgery. She has a private practice in Walnut Creek.

Over the many years in practice has seen a continual increase in the number of patients being harmed due to improperly supervised or unsupervised practice of medicine using lasers. A number of patients filed complaints with the Medical Board and as their treating physician, was asked to represent them at this meeting.

A slide presentation and posters were presented showing the complications of laser surgery.

Several patients suffered third degree burns which resulted in permanent nerve damage. All have suffered from varying degrees of disfigurement and scarring. Several have filed complaints with the California Medical Board, but these complaints have been ignored. All of the cases involve violations of corporate practice of medicine laws in California and the California Medical Board had been alerted to these violations. When they asked for proof of patient harm, that too was provided, but still these businesses were allowed to continue without any enforcement of the current laws and regulations.

Because of that, there continue to be cases such as cases shown of patients who suffered burns resulting from inadequate supervision and many scars. These corporate entities which are in violation of numerous laws in California continue to operate despite the claims being filed with the Medical Board. And just this week, she met two new patients who suffered from the same thing; procedures performed by non-physicians, in these cases, RNs who work out of mini spas that are supposedly supervised by a physician. In the most recent case, she met a gentleman who has severe eye damage and he says that particular facility never has a doctor on site. In fact, nobody in the office ever sees the doctor and in fact they have pre-stamped

prescriptions that they commonly hand out to all the patients without the doctor ever signing or having seen the patient.

Many of these patients have been successful in seeking justice in the legal system but it is unfortunate that most of these cases may have been prevented had the Medical Board acted upon the complaints that were made and worked to enforce the current laws while obvious violations were occurring.

Many, if not all of these corporate laser mini spas are owned and run by non-physicians. They form a so-called medical group run by a medical director that serves as a front to get the appearance that a doctor is running the show. The corporation hires doctors to supervise the many sites. In actuality these mini spas are run by nurses, and rarely is there any involvement from a physician.

Several locations that filed complaints to the Board were treated by non-physicians who were working in mini spas located in shopping malls which the supervising doctor would only visit once or twice a month, and that physician would be supervising sometimes over 13 sites located in numerous cities. In all of the cases, some of the patients never met a doctor, never was evaluated by a doctor, and the doctor was never made available even after the patient requested to see a doctor after complications arose.

What we need is clearly stated clarification of the present laws, and the Medical Board and the Board of Registered Nursing need to adopt a policy, a strict interpretation and heavy enforcement of the rules and regulations.

We need to consider laws that clarify supervision and the boards need to strictly interpret the laws and happily enforce them.

The current scope of practice laws require that nurses, nurse practitioners and PAs need to practice under a doctor's supervision and only perform procedures covered within that position's scope of practice. For example, if a doctor's not insured to perform cosmetic procedures, then personnel working under that doctor cannot be covered. Many doctors and nurses are treating patients with procedures that they are not trained to perform and therefore not covered by insurance, so they are operating bare. For example, as a dermatologist, if I hired a PA who previously worked managing diabetes and they came to my practice, even if she were certified and competent to treat diabetes, I would not be able to have her treat diabetics in my practice because I would not be able to supervise her in that capacity. And by definition, she would then be practicing outside her scope of practice. No matter what a PA or nurse is trained in they are operating outside their scope of practice if they are not being supervised by a doctor who is qualified to serve in that capacity.

There needs to be accurate disclosure of board certification, residency and fellowship training. Many of the patients who suffered harm were misled by fraudulent misrepresentation of a doctor's specialty. They were told that the doctor was a cosmetic specialist when in fact they were colorectal surgeons, internists, GPs, emergency room doctors, urologist, and psychiatrists, anything but a cosmetic specialist. Many of these physicians are members of societies that use laser or cosmetic, in their name and try to misrepresent their membership in the societies as

evidence of credentialing or training. Membership in a society does not qualify as credentialing or training.

Weekend courses and other so-called certification courses are being misrepresented as formal training. Laser companies are not able to provide proper credentialing and training of doctors or non-physicians. A weekend course does not constitute adequate training. A weekend course offered by a laser company on a new device might be adequate for a plastic surgeon or dermatologist who already has the prerequisite training and foundation of knowledge upon which to integrate the new technology into their existing cosmetic practice. These courses assume that the attendees already possess the prerequisite knowledge, education and training. The problem is that non-core positions and non-physicians have been using these weekend courses as a substitute for adequate training. There is no substitute for formalized training. That can only be provided by residency and fellowship programs in credentialed academic centers.

A laser course does not teach a practitioner how to be an expert in evaluation and diagnosis and treatment of the skin. Learning how to operate one laser does not qualify a practitioner to be qualified in the proper clinical application of that device and to be able to treat the possible side effects and complications resulting from that treatment.

The onsite supervision requirement in the original Figueroa bill would not restrict any physician from personally performing cosmetic procedures. The physician still uses their own judgment on what constitutes proper training and takes responsibility for that.

Applying existing scope of practice laws and context of the onsite physician supervision requirement put forth by the Figueroa bill would require that only aesthetically trained physicians be allowed to supervise nurses and PAs. The ER doctor who fell in love with cosmetics would still be allowed to perform cosmetic procedures. Any doctor can choose to perform cosmetic procedures but only aesthetically trained core specialists can adequately supervise nurses and PAs performing those procedures according to the scope of practice laws.

There is currently a severe nursing shortage in California lacking access to needed medical services. Elimination of nurses, nurse practitioners, and PAs working illegally or outside their scope of practice in medi- spas, would help with the nursing shortage and improve access to medical healthcare, much needed medical health care.

Requiring direct onsite physician supervision would not impair access to needed medical services because it's limited to cosmetic and laser procedures. In fact, it would help increase access to needed medical care and improve patient safety because it would help stop the draining of nurses and PAs from needed medical practices.

Strict interpretation and enforcement of existing scope of practice laws already help to prevent this. There needs to be greater clarification of these laws requiring onsite supervision by only aesthetically trained core specialties. Many nurses, nurse practitioners and PAs working in medi-spas are in violation of the scope of practice

laws governing them by working under physicians who are not qualified to supervise cosmetic procedures.

Since it is obvious that their boards are not policing their members, it is necessary to spell out clearly what aesthetically trained specialties are, that are qualified to supervise cosmetic procedures. And furthermore, there needs to be disciplinary action against those that are in violation of their scope of practice.

Cosmetic laser procedures are elective procedures that by definition are not medically necessary. The public would not be disadvantaged by regulation of these services. Having complications from an elective cosmetic procedure is a tragedy. Better to not do it at all if it can't be done properly. The public would be better served by ensuring that cosmetic procedures are performed under the guidance of qualified practitioners.

This is a unique problem. Cosmetic spas are not linked with other medical services. It's not like you see colorectal clinics and spinal centers popping up all over with nurses running them. This would not impact access to all other medical services that is provided by nurses and PAs in appropriate medical settings. This is a nationwide problem. Florida passed a law requiring only derms and plastics could supervise cosmetic and laser clinics. New York is currently considering a bill requiring onsite physician supervision over cosmetic laser procedures. Six other states have already required direct onsite physician supervision for quite some time.

These are the reasons I'm in support of the proposed legislation requiring onsite physician supervision of cosmetic and laser procedures. I do not believe that this new regulation would put undo burden on physicians and would not restrict nurses, nurse practitioners and PAs in an undo manner. I am in support of the original Figueroa bill 1423 which calls for direct onsite supervision by physician and furthermore should be defined to be only aesthetically trained core specialties that are allowed to supervise cosmetic procedures. That would be consistent with our current scope of practice laws, and I cannot stand to see yet another patient harmed walking into my office.

Thank you for the opportunity to speak.

Consumer

Steven H. spoke as a consumer and he is representing a group of people who became victims of unsupervised or improperly supervised laser procedures. He was requested by the victims to discuss their experiences and the failure of the governing boards to protect them.

I first want to state my support for Senator Figueroa's original bill that would require onsite direct supervision of laser cosmetic treatments. I would like to add that most would be greatly elevated if the governing boards would actively assist in enforcing present law.

Public Comment

None

5.0 Issues for discussion at future meetings, to be held October 31, 2007 in San Diego, California

The next forum will again provide opportunity for interested parties to speak regarding this subject. Staff has been directed to prepare an issue paper on current laws and their enforcement.

Dr. Solomonson adjourned the meeting at approximately 11:20 am.